

Claims

What is claimed is:

5           1. An isolated polynucleotide encoding a plurality of *Mycobacterium tuberculosis* antigens.

2. A vector comprising the polynucleotide of claim 1.

10           3. A composition of matter comprising a gold particle coated with a plurality of vectors according to claim 2.

4. A composition comprising the vector of claim 2 and a pharmaceutically acceptable excipient.

15           5. A composition comprising at least two polynucleotides, wherein each polynucleotide encodes one *M. tuberculosis* antigen.

20           6. A composition according to claim 5 further comprising a pharmaceutically acceptable excipient.

sub A1           7. A method for eliciting an immune response against *M. tuberculosis* in a subject, said method comprising administering to the subject a vector according to claim 2 at sufficient levels to elicit an immune response.

sub B1           8. The method of claim 7, further comprising administering at least one secondary composition in a boosting step to said subject.

30           9. The method of claim 8 wherein the secondary composition comprises at least one protein antigen.

sub A2  
10. The method of claim 9, wherein the at least one protein antigen comprises culture filtrate proteins of *M. tuberculosis*.

11. The method of claim 9, wherein the at least one protein antigen comprises  
5 isolated subunits of *M. tuberculosis* proteins.

12. The method of claim 8, wherein the secondary composition comprises a live attenuated vaccine.

sub 10  
A3  
13. The method of claim 12, wherein the live attenuated vaccine is derived from a *M. tuberculosis* species.

sub B1  
14. The method of claim 13, wherein the live attenuated vaccine is BCG.

sub 15  
A4  
15. A method for eliciting an immune response against *M. tuberculosis* in a subject, said method comprising administering to the subject a composition according to claim 5 at sufficient levels to elicit an immune response.

sub B1  
20  
16. The method of claim 15, further comprising administering at least one secondary composition in a boosting step to said subject.

17. The method of claim 16, wherein the secondary composition comprises at least one protein antigen.

sub A5  
18. The method of claim 17, wherein the at least one protein antigen comprises culture filtrate proteins of *M. tuberculosis*.

19. The method of claim 17, wherein the at least one protein antigen comprises isolated subunits of *M. tuberculosis* proteins.

20. The method of claim 16, wherein the secondary composition comprises a live attenuated vaccine.

21. The method of claim 20, wherein the live attenuated vaccine is derived from a *M. tuberculosis* species.

22. The method of claim 21, wherein the live attenuated vaccine is BCG.

23. The method of claim 7 or claim 15, wherein the administering is transdermal administration.

24. The method of claim 7 or claim 15, wherein the subject is human.

25. A method for eliciting an immune response to *M. tuberculosis* in a subject, said method comprising:

(a) providing a core carrier coated with a composition according to claim 2; and  
(b) administering the coated core carrier to the subject using a particle-mediated delivery technique, wherein the *M. tuberculosis* antigens are expressed in the subject at sufficient levels to elicit an immune response.

26. The method of claim 25, wherein the core carrier has an average diameter of about 0.5 to about 5  $\mu\text{m}$  and a density sufficient to allow delivery into the subject.

27. The method of claim 25, wherein the core carrier is comprised of a metal.

28. The method of claim 27, wherein the metal is gold.

29. The method of claim 25, wherein step (b) is repeated.

30. The method of claim 25, further comprising administering at least one secondary composition in a boosting step to said subject.

31. The method of claim 30, wherein the secondary composition comprises at least one protein antigen.

32. The method of claim 31, wherein the at least one protein antigen comprises culture filtrate proteins of *M. tuberculosis*.

33. The method of claim 31, wherein the at least one protein antigen comprises isolated subunits of *M. tuberculosis* proteins.

34. The method of claim 30, wherein the secondary composition comprises a live attenuated vaccine.

35. The method of claim 34, wherein the live attenuated vaccine is derived from a *M. tuberculosis* species.

36. The method of claim 35, wherein the live attenuated vaccine is BCG.

37. A method for eliciting an immune response to *M. tuberculosis* in a subject, said method comprising:

(a) providing a core carrier coated with a vector according to claim 5; and

(b) administering the coated core carrier to the subject using a particle-mediated delivery technique, wherein the *M. tuberculosis* antigens are expressed in the subject at sufficient levels to elicit an immune response.

38. The method of claim 37, wherein the core carrier has an average diameter of about 0.5 to about 5  $\mu\text{m}$  and a density sufficient to allow delivery into the subject.

SVB  
B1  
5 39. The method of claim 37, wherein the core carrier is comprised of a metal.

40. The method of claim 39, wherein the metal is gold.

41. The method of claim 37, wherein step (b) is repeated.

42. The method of claim 37, further comprising administering at least one secondary composition in a boosting step to said subject.

10 43. The method of claim 42, wherein the secondary composition comprises at least one protein antigen.

SVB  
A1  
15 44. The method of claim 43, wherein the at least one protein antigen comprises culture filtrate proteins of *M. tuberculosis*.

45. The method of claim 43, wherein the at least one protein antigen comprises isolated subunits of *M. tuberculosis* proteins.

20 46. The method of claim 42, wherein the secondary composition comprises a live attenuated vaccine.

SVB  
A2  
25 47. The method of claim 46, wherein the live attenuated vaccine is derived from a *M. tuberculosis* species.

SVB  
B1  
48. The method of claim 47, wherein the live attenuated vaccine is BCG.

49. The method of claim 25 or claim 37, wherein the subject is human.

30 50. A method of eliciting an immune response in a subject, said method comprising transfecting cells of the subject with a polynucleotide encoding at least two

*M. tuberculosis* antigens, wherein said transfecting is carried out under conditions that permit expression of said antigens within said subject, and said expression is sufficient to elicit an immune response against *M. tuberculosis*.

5           51. A method of eliciting an immune response in a subject, said method comprising transfecting cells of the subject with a cocktail of polynucleotides, each polynucleotide of the cocktail encoding one or more *M. tuberculosis* antigens, wherein said transfecting is carried out under conditions that permit expression of said antigens within said subject, and said expression is sufficient to elicit an immune response against  
10 *M. tuberculosis*.

          52. The method of claim 50 or claim 51, wherein the transfecting step is carried out *in vivo* using a particle-mediated transfection technique.

15           53. The method of claim 50 or claim 51, wherein the transfecting step is carried out *ex vivo* to obtain transfected cells which are subsequently introduced into said subject.

          54. The method of claim 50 or claim 51, further comprising administering BCG to said subject.

20           55. The method of claim 50 or claim 51, wherein the subject is human.